

Medical treatment of adenoid hypertrophy with mometasone furoate monohydrate nasal spray

علاج تضخم الغدانية باستخدام رذاذ الأنف (الموميثازون فيورويت مونوهيدرات)

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خلفية: يتحدد الغدانية وفقاً لدرجة انسداد مجرى الهواء في الأنف وباختيار العلاج الجراحي ، ينبغي تقييم وتحليل المخاطر المنافع الفردية للمرضى من حيث مضاعفات التخدير العملية الجراحية. على الرغم من أن هناك عدد قليل من الخيارات العلاجية البديلة، يعتبر الاستخدام الموضعي للستيرويد داخل الأنف نهجاً غير على هذا الأساس استندت هذه الدراسة.

الهدف : تقييم تأثير استخدام علاج الموميثازون فيورويت مونوهيدرات () على تضخم الغدانية وتحديد عدد المرضى الذين سيتم استبعادهم من العلاج الجراحي

منهجية: أجريت هذه الدراسة في مدينة الصدر الطبية في محافظة النجف للفترة من 31 ديسمبر 2012 ولغاية 31 ديسمبر 2013. تم تقسيم المرضى عشوائياً مجموعتين . عولجت بعقار الموميثازون يورويت مونوهيدرات (عن طريق) وبجرعة دوائية مقدارها 100 ميكروغرام / يوم (50 ميكروغرام لكل (12) إما المجموعة الثانية فتم إعطاؤها ملحيه (صوديوم كلورايد) عن طريق أيضا و لنفس الفترة الزمنية. تم استدعاء جميع المرضى لـ 4 أسابيع. : 12 لوحظ وجود تحسن مميز لستيرويد

بالقطرات الملحية من حيث انسداد الأنف والتنفس عن طريق الفم حيث انخفض بالستيرويد 12.82 بينما كان التغير الحاصل في المجموعة الأخرى طفيفا من 12.53 إلى 12.18 . في هذه الدراسة، يتم فحص تأثير الموميثازون يـ يت مونوهيدرات () غدانية وهذه الطريقة توفر بديلا فعالا للعلاج الجراحي الأطفال الذين يعانون من أعراض انسداد الأنف والتنفس عن طريق الفم الناتج من تضخم الغدانية تطبيق هذه الدراسة 77.2 هم

التوصيات: من الضروري تحديد مدى الاستفادة من استخدام الستيرويدات كعلاج موضعي داخل الأنف للأطفال الذين يعانون من انسداد الأنف الناتج عن تضخم الغدانية

: الغدانية الموميثازون يـ يت مونوهيدرات ()

Abstract

Background: Treatment of adenoid hypertrophy is generally planned in accordance with the degree of airway obstruction and related morbidity. If surgical treatment is indicated, the individual risk/ benefit analysis of patients should be assessed in terms of anesthetic and postoperative complications.

Although there are few alternative treatment options, intranasal steroid applications may be considered as a nonsurgical approach in less serious cases and have been presented in this study.

Objectives of the study: To assess the effect of mometasone furoate monohydrate nasal spray on adenoid hypertrophy and to determine how many patients will be excluded from the surgical treatment.

Patients and methods: A prospective, randomized, placebo controlled study was done in Al-Sader medical city in Najaf from the period of 31 of Dec. 2012 to 31 of Dec. 2013. Patients indicated for surgery were randomly divided into two groups. The study group was treated by mometasone furoate monohydrate nasal spray (NSS-nasal steroid spray) of 100 micrograms/day (50 micrograms for each nostril) for 12 weeks. The control group was treated by normal saline (NS) nasal drops in the same way. All the patients were followed-up every 4 weeks.

Results: At the end of 12 weeks, statistically significant improvement ($p < 0.05$) was observed in the NSS treated group compared to the NS treated group in terms of nasal airway obstruction, mouth breathing, and night cough. At the end of 12 weeks, the average total symptoms score of the NSS treated group dropped from 12.82 to 4.75 while the NS treated group's score changed from 12.53 to 12.18. After 12 weeks of NSS treatment the initial adenoid/choana (A/C) rate had dropped from 87.14 to 51.42% and a total decrease of 35.72% was observed. After 12 weeks of NS treatment the A/C rate dropped from 87.5 to 85% and a total decrease of 2.5% was observed.

Conclusions: Treatment with mometasone furoate monohydrate nasal spray provides an effective alternative to surgical treatment in children with adenoid hypertrophy. With the protocol applied in this study 77.2% of the patients were excluded from the surgery and removed from the surgical waiting list.

Recommendations: The reliability of nasal steroids for the pediatric population is widely recognized. Although the mechanism itself has not yet been clearly and totally explained. We recommend that it is important to determine the role of intranasal corticosteroids in treating children with adenoid hypertrophy.

Keywords: adenoid hypertrophy, mometasone furoate monohydrate nasal spray

INTRODUCTION

Adenoid is a lymphoid tissue located in the roof and posterior wall of the nasopharynx. Adenoid hypertrophy is a common childhood disease. An enlarged adenoid can occlude the choana, especially when sleeping in a supine position. Symptoms due to airway obstruction like mouth breathing, hyponasal speech and snoring in children are observed. ^[1] It may also cause otitis media with effusion and accompanying conductive hearing loss and in the most serious cases, obstructive sleeping apnea and accompanying growth retardation and cor-pulmonale. ^{[2],[3]} Adenoid hypertrophy treatment for children is determined according to the degree of airway obstruction and related morbidity. If surgical treatment is indicated, the individual risk/ benefit analysis of patients should be assessed in terms of anesthetic and postoperative complications. Although there are few alternative treatment options, these may be considered as a nonsurgical approach in less serious cases. ^[3] Accordingly, studies about intranasal steroid applications under various protocols have been presented in the literature .

OBJECTIVES

To assess the effect of mometasone furoate monohydrate nasal spray on adenoid hypertrophy and to determine how many patients will be excluded from the surgical treatment.

PATIENTS AND METHODS

This is a prospective, randomized, placebo-controlled study of 65 patients with a symptomatic and surgically indicated adenoid hypertrophy. The study had been done in Al-Sader medical city in Najaf from the period of 31 of Dec. 2012 to 31 of Dec. 2013. Consent was obtained from the patients' parents after they were informed about the objectives of the study and the use of the drugs. Patients needed to meet the following inclusion criteria in order to enter the study

- (1)adenoid size occluding 75% of the nasopharynx, as determined with nasal endoscopy;
- (2) age between 5 to 15 years;
- (3) symptoms consistent with adenoid hypertrophy lasting for at least 6 months;
- (4) no previous adenoidectomy.

Patients with one or more of the following criteria were excluded from the study

- (1)Children with concomitant tonsillar hypertrophy,
- (2)Positive history of allergy or atopy,
- (3)Upper respiratory infection within the past 2 weeks,
- (4)Nasal anatomic anomalies (e.g., nasal septum deviation),
- (5)Sinonasal diseases such as hypertrophy of inferior turbinate and/or nasal polyposis,
- (6)Craniofacial malformations including cleft lip/cleft palate,
- (7)Genetic diseases (e.g., Down syndrome), neurologic disorders, cardiovascular diseases, and immunodeficiency,

(8)History of epistaxis or hypersensitivity to steroids,

At the beginning, clinical history was obtained from the parents with a questionnaire and each child underwent physical evaluation and nasal endoscopy. Patient history included age, gender, history and family history of atopy or allergy, and use of drugs. Symptoms such as nasal obstruction, nasal discharge, cough, snoring, and obstructive sleep apnea were also evaluated at the first and at each subsequent visit, by using a clinical scoring system ranging from 0 to 3 (0 = absent; 1 = occasional; 2 = frequent; 3 = daytime and nighttime symptoms).^[4] In this way, we gave each aforementioned symptom a score related to severity. All scores were summed to obtain an overall symptom score for each patient.

Nasal endoscopy was performed to estimate adenoid size and to identify other sinonasal disorders. After local anesthesia administration and decongestion of the nasal mucosa for 10 minutes with cotton pledgets soaked in xylocain, endoscopic examination was conducted by using a rigid (2.7-mm diameter) or flexible endoscope, according to the compliance of the child. Choanal openings from top to bottom were graded (grade 1–4)^[5], and determined as:

1st grade: only top segment of the choana is obstructed (adenoid/choana (A/C)rate is %25)

2nd grade: upper half of the choana is obstructed(A/C rate is %50)

3rd grade: Eustachian tube opening is partially obstructed (A/C rate is %75)

4th grade: the choana is almost completely obstructed (A/C rate is 100%).

Patients indicated for surgery were then randomly divided into two groups. The first group was treated by mometasone furoate monohydrate nasal spray (NSS- nasal steroid spray) of 100 micrograms/day (50 micrograms for each nostril) for 12 weeks. The other group was treated by normal saline (NS) nasal drops . All the patients were called for follow-up every 4 weeks.

SPSS 16.0 software was used for statistical analysis. When comparing the groups, the independent sample t-test was applied. p values <0.05, were accepted as statistically significant.

RESULTS

The demographic data for 65 patients is presented in Table (1),

Table (1)	Age and gender distribution			
Group	No. of pt.	Age (mean)	Male	Female
NSS	35	5-14 yr.(8.6)	13	22
NS	30	5-13 yr. (8.5)	17	13
Total	65		30	35

This table shows that among the total 65 patients, 30 patients were males and 35 were females. Also it shows that 35 patients were treated by the nasal steroid spray(NSS). Their age ranging from 5 to 14 years with mean age equal to 8.6

years. Among the 30 patients (control group) who were treated by the nasal saline drops(NS), their age ranging from 5 to 13 years with mean age equal to 8.5 years.

Symptoms	Symptoms score distribution			
	Average score before treatment		Average score after treatment (after 12 weeks)	
	NSS	NS	NSS	NS
Nasal discharge	2.74	2.8	0.85	2.53
Mouth breathing	2.85	2.7	1	2.83
Snoring	2.83	2.83	0.8	2.83
Night cough	2	1.8	1.42	1.66
Sleep apnea	2.4	2.4	0.68	2.33
Total	12.82	12.53	4.75	12.18
P value			0.004	0.355

Table (2) shows that at the beginning of the treatment and at the end of the 12 weeks follow-up period, symptoms of nasal airway obstruction were assessed. By taking all the symptoms into consideration, the average total symptoms score for each group was calculated and compared, (Fig. 1).

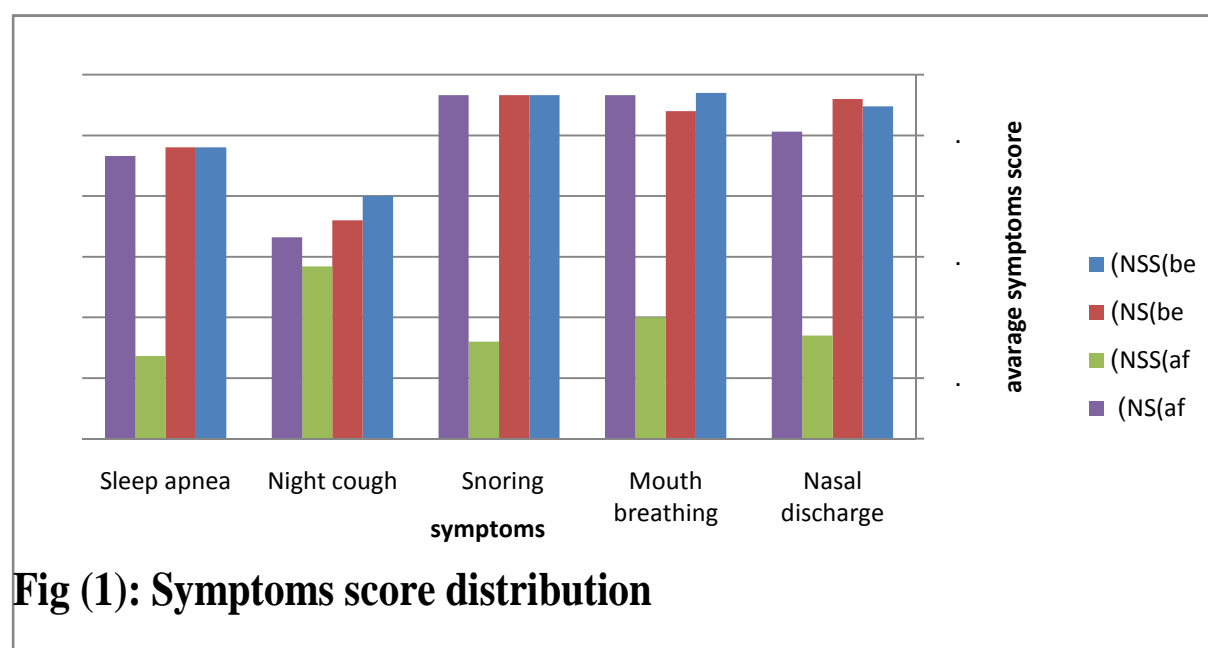


Fig (1): Symptoms score distribution

For both NSS and NS groups, the total symptoms scores were nearly similar prior to the treatment. At the end of the 12 weeks, the average total symptoms score of the NSS treated group dropped from 12.82 to 4.75 with a statistically significant difference ($t= 6.13$, $p =0.004$), while the NS treated group's score

changed from 12.53 to 12.18 with a non significant difference ($t= 1.04$, $p = 0.355$).

Figure (2) shows that the adenoid/choana (A/C) rate of the NSS treated group after 12 weeks dropped from 87.14% to 51.42% and a total decrease of 35.72% was observed. For the NS treated group the A/C rate after the 12 weeks dropped from 87.5% to 85% and a total decrease of 2.5% was observed.

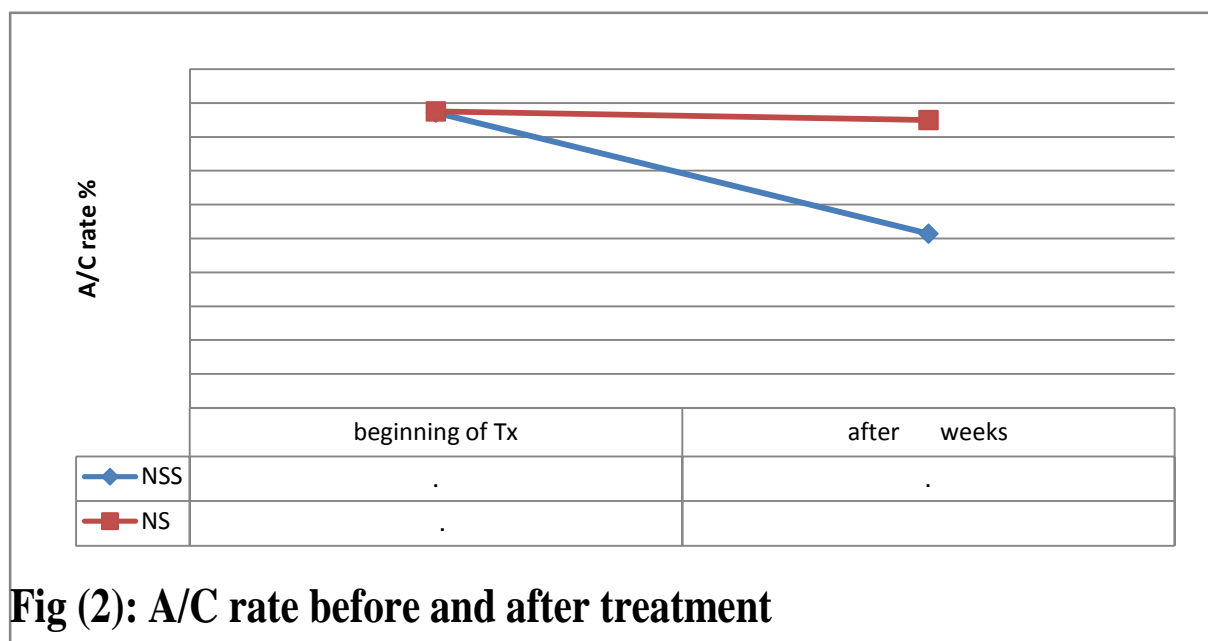


Fig (2): A/C rate before and after treatment

Table (3)	Surgical need among the two groups		
Group	No. of pt.	Not need surgery(%)	Need surgery(%)
NSS	35	27(77.2)	8(22.8)
NS	30	0(0.0)	30(100)
Total	65	27	38

Table (3) shows that among the 35 patients who had NSS treatment, 27(77.2%) patients were not longer needing for surgery. Adenoidectomy was applied to 4 (11.4%) patients and the remaining 4 (11.4%) were informed of their ongoing need for surgery but their parents refused the operation. Of the 30 patients who were treated with normal saline, all of them (100%) underwent adenoidectomy.

DISCUSSION

Adenoid hypertrophy is probably the most frequent pathologic condition occurring in the pediatric age group. It leads to different clinical manifestations according to adenoid size. Bilateral nasal obstruction is a primary complaint that can be associated with different sleep disorders, ranging from snoring to OSAS^[6]. In such a situation, patients typically complain of both nighttime and daytime behavioral illnesses (i.e., intermittent sleep, sleepwalking, morning headaches, difficulty concentrating, daytime sleepiness, enuresis, slow feeding,

and poor growth), which may lead to cardiorespiratory syndromes such as cor pulmonale in extreme cases.^[7] Rhinorrhea, mouth-breathing, hyponasal speech, and cough can also be observed in patients with adenoid hypertrophy. At present, adenoid hypertrophy is one of the most frequent indications for surgery in childhood, and adenoidectomy commonly is considered definitive treatment for nasopharyngeal obstruction.^[8] Nevertheless, this surgical technique has been the subject of some criticism. Paulussen et al^[9] hypothesized that the removal of adenoid lymphatic tissue could have a negative impact on the systemic immunologic system. Moreover, immediate postoperative or late bleeding is observed in 1% of children who undergo adenoidectomy. Furthermore, it is well demonstrated that adenoids may recur after surgery in 10% to 20% of cases.^[10]

In our study, the effect of mometasone furoate monohydrate nasal spray on adenoid hypertrophy was assessed to determine how many patients will be excluded from the surgical treatment. At the end of 12 weeks treatment, a statistically significant improvement in nasal airway obstruction symptoms was observed in the nasal steroid spray(NSS) treated group compared to the normal saline drops(NS) control group ($p < 0.05$). Patients' average total symptoms score dropped from 12.82 to 4.75 in the NSS group and from 12.53 to 12.18 in the control group. The average total symptom score of the NSS treated group decreased by 63%. Regarding the adenoid size, after 12 weeks of treatment, the decrease in the A/C rate was 35.72% in the NSS group and only 2.5% in the NS group.

In 2005, Brouillette et al^[11] tested the efficacy of another intranasal steroid treatment for OSAS in a randomized, placebo-controlled clinical study by studying the use of fluticasone propionate nasal spray versus placebo for 25 children affected by OSAS, as demonstrated with polysomnography. After treatment, the mixed/obstructive apnea/ hypopnea index, frequency of hemoglobin desaturation, and respiratory movement/arousals decreased more in the fluticasone-treated group, compared with the placebo- treated group. Moreover, improvements in symptom scores were observed for 69% of children who received fluticasone.

In 2003, Criscuoli et al^[12] by studying 53 children, they reported on the long-term outcomes of treatment with aqueous nasal beclomethasone for patients with adenotonsillar hypertrophy. Twenty four patients exhibited improvement after 2 weeks of steroid treatment, and an additional 24 weeks of therapy at a lower steroid dose maintained clinical improvement for 45.8% of those patients.

Recently, Cengel and Akyol^[13] assessed the efficacy of Mometasone furoate monohydrate in the treatment of adenoid hypertrophy, in a prospective, controlled, randomized, clinical trial. Of 122 patients enrolled, 67 received intranasal Mometasone furoate monohydrate (100 mcg/day) therapy for 6 weeks, whereas 55 patients were assigned to the control group. After treatment, a significant decrease of the adenoid mass was observed for 67.2% of the study

group, whereas the clinical situation was unchanged in the control group. They reported that the A/C rate decreased by 50%.

Ciprandi et al^[4] showed significant decrease ($p < 0.05$) in average adenoid size after 8 weeks of Flunisolide treatment compared to normal saline treatment.

Berlucchi et al^[14] in a placebo-controlled study observed that the average symptoms score dropped from 11 to 3 in the group treated by Mometasone furoate spray and from 10 to 9 in the placebo treated control group. They also observed a 20% decrease in average choanal obstruction in the Mometasone group and 0.0% in the placebo group

Lepcha et al^[15] reported, on the contrary to other studies, that although there was a decrease in symptom scores after 12 weeks with Beclomethasone treatment, it did not constitute a statistically significant difference comparing to placebo control group's scores.

Brouillette et al^[11] also reported that reduction in adenotonsillar hypertrophy caused by Fluticasone spray did not show statistically significant difference compared to placebo.

Regarding the need for surgery after the nasal steroid treatment of the adenoid hypertrophy, our study showed that among the 35 patients who had NSS treatment, 27(77.2%) patients were not longer needing for surgery. Adenoidectomy was applied to 4 (11.4%) patients and the remaining 4 (11.4%) were informed of their ongoing need for surgery but their parents refused the operation. Of the 30 patients who were treated with normal saline, all of them (100%) underwent adenoidectomy.

Criscuoli et al^[12] reported in their first long-term study that out of a total 24 patients who responded well to the initial treatment, 13 patients (54%) were still in need of surgery. Berlucchi et al^[14] informed that after Mometasone furoate treatment only 2 of 39 patients who were indicated for adenoidectomy underwent the surgery.

Corticosteroids are generally well tolerated in children. In our study, for each nostril a maximum dose of 50 microgram/day, and for each patient total dose of 100 micrograms/day, was used for 12 weeks. We have not observed any side effects in our patients.

CONCLUSION

This study provides an effective alternative to surgical treatment in children with adenoid hypertrophy. With the protocol applied in this study 77.2 % of the patients were no longer needing the surgery therefore they were removed from the surgical waiting list. Intranasal corticosteroids are well tolerated by children; however, the most appropriate drug, the most efficient dose and optimal treatment duration continue to be investigated and determined by way of further prospective and randomized studies.

RECOMMENDATIONS

The reliability of nasal steroids for the pediatric population is widely recognized. Although the mechanism itself has not yet been clearly and totally explained. We recommend that it is important to determine the role of intranasal corticosteroids in treating children with adenoid hypertrophy.

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